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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Alan J Grant Esq
Carella Byrne Bain Gilfillan Cecchi
Stewart & Olstein
6 Becker Farm Road
Roseland, NJ 07068

EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 06/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/590,991

Applicant(s)

ADAMOU ET AL.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4-15, 17-23 and 25-32 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) 5-15, 17-22 and 25-32 ~~is/are~~ are withdrawn from consideration.
- 5) ☒ Claim(s) 23 ~~is/are~~ allowed.
- 6) ☒ Claim(s) 1 and 4 ~~is/are~~ rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Serial No: 09/590,991
Art Unit: 1645

Response to Applicants' Amendment

Applicants' Amendments

- 1) Acknowledgment is made of Applicants' amendments filed 01/09/04 and 03/31/04 in response to the non-final Office Action mailed 10/23/03.

Status of Claims

- 2) Claims 24 and 16 have been canceled via the amendment filed 01/19/04 and 03/31/04.
Claims 1, 4 and 23 have been amended via the amendment filed 01/19/04 03/31/04.
Claims 1, 4-15, 17-23 and 25-32 are pending.
Claims 1, 4 and 23 are under examination.

Prior Citation of Title 35 Sections

- 3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

- 4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Maintained

- 5) The objection to the drawings made in paragraph 3 of the Office Action mailed 12/21/01 (paper no. 6) is maintained for reasons set forth therein.

Rejection(s) Moot

- 6) The rejection of claim 24 made in paragraph 22 of the Office Action mailed 10/23/03 under 35 U.S.C. § 112, first paragraph, as containing inadequate written description is, moot in light of Applicants' cancellation of the claim.

- 7) The rejection of claim 24 made in paragraph 23 of the Office Action mailed 10/23/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.

Rejection(s) Withdrawn

- 8) The rejection of claims 1 and 23 made in paragraph 6 of the Office Action mailed 12/21/01 (paper no. 6) and maintained in paragraph 19 of the Office Action mailed 10/23/03

under U.S.C. § 112, first paragraph, as being non-enabled, is withdrawn in light of Applicants' amendments to the claims.

9) The rejection of claim 23 made in paragraph 20 of the Office Action mailed 10/23/03 under 35 U.S.C. § 112, first paragraph, is withdrawn in light of Applicants' amendments to the claim.

10) The rejection of claims 1 and 4 made in paragraph 21 of the Office Action mailed 10/23/03 under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is withdrawn in light of Applicants' amendments to the base claim.

11) The rejection of claim 23 made in paragraph 22 of the Office Action mailed 10/23/03 under 35 U.S.C. § 112, first paragraph, as containing inadequate written description, is withdrawn in light of Applicants' amendment to the claim.

12) The rejection of claims 1, 4 and 23 made in paragraph 23 of the Office Action mailed 10/23/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims and/or the base claim(s).

Rejection(s) under 35 U.S.C. § 101

13) 35 U.S.C. § 101 states:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this cycle.

14) Claims 1 and 4 are rejected under 35 U.S.C § 101 as being directed to a non-statutory subject matter.

Claims 1 and 4 do not sufficiently distinguish the claimed polypeptide over naturally occurring polypeptides, proteins, as they exist naturally, because the claims do not particularly point out any non-naturally occurring differences between the claimed product(s) and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of --an isolated polypeptide ---; or --A purified polypeptide--; or --An isolated and purified polypeptide-- if descriptive support exists for such a limitation in the instant application,

as originally filed. See MPEP 2105.

Rejection(s) under 35 U.S.C § 112, First Paragraph (New Matter)

15) Claims 1 and 4 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1 and 4, as amended, include the broad limitation: 'a carrier'. However, there is no descriptive support in the specification, as originally filed, for an immunogenic composition or a vaccine comprising the polypeptide of SEQ ID NO: 6 and a generic 'carrier'. A generic carrier includes within its scope polymeric carriers, protein carriers, polysaccharide carriers etc. for which Applicants do not have descriptive support in the specification. The original claim 16, and paragraphs bridging pages 13 and 14 as well as pages 19 and 20 recite a carrier of narrower scope, i.e., --a pharmaceutically acceptable carrier -- or a-- pharmaceutical carrier--. Therefore, the above-identified limitation in claims 1 and 4 are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to point to the descriptive support in the specification as filed, for the limitation(s), or to remove the new matter from the claim(s).

Rejection(s) under 35 U.S.C. § 102

16) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

17) Claims 1 and 4 are rejected under 35 U.S.C. § 102(e)(2) as being anticipated by Johnson *et al.* (US 6,582,706, filed 12/21/1998).

The term 'vaccine' represents the intended use of the product and therefore is not given

any patentable weight. It is noted that the polypeptide claimed in claims 1 and 4 are not required to be purified or isolated.

Johnson *et al.* disclosed the serotype 4 Norway strain of *S. pneumoniae* (see paragraph bridging columns 10 and 11), a composition comprising 550 or 862 CFU *S. pneumoniae* strain SJ2 serotype 6B (see lines 5 and 56-61 in column 3), and 23 pneumococcal strains in water (i.e., carrier) and cell lysates of these strains (see Example 3). Since the claimed polypeptide is not required to be isolated, Johnson's serotype 4 Norway strain of *S. pneumoniae* inherently containing the polypeptide of SEQ ID NO: 6 anticipates the instant claims. Due to the presence of the polypeptide of SEQ ID NO: 6, such whole cells or cell lysates of pneumococci are expected to be immunogenic and protective in a mammal. The Office's position that the prior art composition is the same as the instantly claimed composition is based on the fact that the prior art serotype 4 Norway strain of *S. pneumoniae* and *S. pneumoniae* strain SJ2 serotype 6B are the same strains that are used in the instant specification as described in Example 1 of the specification. Immunogenicity and the ability to induce protective antibodies in a mammal against *S. pneumoniae* are viewed as inherent properties inseparable from the prior art composition.

Claims 1 and 4 are anticipated by Johnson *et al.*

Remarks

18) Claims 1 and 4 stand rejected. Claim 23 is allowed.

19) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

20) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. The Examiner can normally be reached on Monday to Friday from 7.45 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system. A message

may be left on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

June, 2004


S. DEVI, PH.D.
PRIMARY EXAMINER